

Food and Drug Administration, HHS

§ 822.3

- 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?
- 822.13 [Reserved]
- 822.14 May I reference information previously submitted instead of submitting it again?
- 822.15 How long must I conduct postmarket surveillance of my device?

Subpart D—FDA Review and Action

- 822.16 What will you consider in the review of my submission?
- 822.17 How long will your review of my submission take?
- 822.18 How will I be notified of your decision?
- 822.19 What kinds of decisions may you make?
- 822.20 What are the consequences if I fail to submit a postmarket surveillance plan, my plan is disapproved and I fail to submit a new plan, or I fail to conduct surveillance in accordance with my approved plan?
- 822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?
- 822.22 What recourse do I have if I do not agree with your decision?
- 822.23 Is the information in my submission considered confidential?

Subpart E—Responsibilities of Manufacturers

- 822.24 What are my responsibilities once I am notified that I am required to conduct postmarket surveillance?
- 822.25 What are my responsibilities after my postmarket surveillance plan has been approved?
- 822.26 If my company changes ownership, what must I do?
- 822.27 If I go out of business, what must I do?
- 822.28 If I stop marketing the device subject to postmarket surveillance, what must I do?

Subpart F—Waivers and Exemptions

- 822.29 May I request a waiver of a specific requirement of this part?
- 822.30 May I request exemption from the requirement to conduct postmarket surveillance?

Subpart G—Records and Reports

- 822.31 What records am I required to keep?
- 822.32 What records are the investigators in my surveillance plan required to keep?
- 822.33 How long must we keep the records?
- 822.34 What must I do with the records if the sponsor of the plan or an investigator in the plan changes?

- 822.35 Can you inspect my manufacturing site or other sites involved in my postmarket surveillance plan?
- 822.36 Can you inspect and copy the records related to my postmarket surveillance plan?
- 822.37 Under what circumstances would you inspect records identifying subjects?
- 822.38 What reports must I submit to you?

AUTHORITY: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

SOURCE: 67 FR 38887, June 6, 2002, unless otherwise noted.

Subpart A—General Provisions

§ 822.1 What does this part cover?

This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:

(a) Failure of the device would be reasonably likely to have serious adverse health consequences;

(b) The device is intended to be implanted in the human body for more than 1 year; or

(c) The device is intended to be used outside a user facility to support or sustain life. If you fail to comply with requirements that we order under section 522 of the act and this part, your device is considered misbranded under section 502(t)(3) of the act and you are in violation of section 301(q)(1)(C) of the act.

§ 822.2 What is the purpose of this part?

The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

§ 822.3 How do you define the terms used in this part?

Some of the terms we use in this part are specific to postmarket surveillance and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation